

EXPRESS MAIL LABEL NO.: EV 333487310

PATENT

Attorney Docket No. 12636.330.201

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application)

PATENT APPLICATION

Inventor(s): RUBINFELD, Joseph et al.)

Art Unit: 1642

Application No.: 10/613,222)

Examiner: Nickol, Gary B.

Filed: July 3, 2003)

Title: Restoring cancer-suppressing functions to
 neoplastic cells through DNA
 hypomethylation)

Commissioner of Patents
 P.O. Box 1450
 Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. §1.97

Sir:

Listed below or on an attached Form PTO-1449 is information known to applicant(s). A copy of each listed publication and U.S. and foreign patent, except for pending U.S. applications, is being submitted herewith, along with a concise explanation of information in a foreign language, if any, pursuant to 37 C.F.R. §1.97-1.98.

Applicants respectfully request that the listed information be considered by the Examiner and be made of record in the above-identified application. If form PTO-1449 is enclosed, the Examiner is requested to initial and return it in accordance with MPEP §609.

Applicant(s) reserve(s) the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement is not intended to represent that a search has been made or that the information cited in the statement is, or is considered to be, material to patentability as defined in §1.56.

- ☒ This statement qualifies under 37 C.F.R. §1.97, subsection (b) because (check all that apply):
- ☐ (1) It is being filed within 3 months of the application filing date and is other than a continued prosecution application under § 1.53(d)
-- OR --
 - ☐ (2) It is being filed within 3 months of entry of a national stage
-- OR --
 - ☒ (3) It is being filed before the mail date of the first Office Action on the merits
-- OR --
 - ☐ (4) It is being filed before the mailing of a first Office Action after the filing of a request for continued examination under § 1.114.
- ☐ 37 C.F.R. §1.97(c). If this statement is being filed after the latest of: (1) three months beyond the filing date of a national application; (2) three months beyond the date of entry of the national stage as set forth in §1.491 in an international application; or (3) the mailing date of a first Office action on the merits, but before the mailing date of the earlier of a final office action under §1.113 or a notice of allowance under §1.311, then:
- ☐ a certification as specified in §1.97(e) is provided below; or
 - ☐ a fee of \$180.00 as set forth in §1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this statement.
- ☐ 37 C.F.R. §1.97(d). If this statement is being filed after the mailing date of the earlier of a final office action under §1.113 or a notice of allowance under §1.311, but before payment of the issue fee, then:
- A. a certification as specified in §1.97(e) is completed below; and
 - B. a petition under 37 C.F.R. §1.97(d) requesting consideration of this statement is submitted herewith; **and**
 - C. a fee of \$130.00 as set forth in §1.17(i)(1) is authorized below, enclosed, or included with the payment of other papers filed together with this statement.
- ☒ Copies of each of the references listed on the attached Form PTO-1449 are enclosed herewith.
- ☐ Copies of references listed on the attached Form PTO-1449 are enclosed herewith EXCEPT THAT:
- ☐ In view of the voluminous nature of references, and the likelihood that these references are available to the Examiner in the file history of the parent application (Serial No.), copies are not enclosed herewith.
 - ☐ If any of the foregoing publications are not available to the Examiner, Applicant will endeavor to supply copies at the Examiner's request.
 - ☐ Copies of only foreign patent documents and non-patent literature are enclosed in accordance with 37 CFR 1.98 (a)(2). (The U.S. patents and each U.S. patent application publication listed on the attached Form PTO-1449 are not enclosed

because this U.S. patent application was filed after June 30, 2003 or this international application has entered the national stage under 35 USC §371 after June 30, 2003 (see USPTO waiver of requirement under 37 CFR 1.98 (a)(2)(i).

- ☐ There are no listed references which are not in the English language.
- ☐ The relevance of those listed references which are not in the English language is as follows:
- ☐ Attached are copies of search report(s) from corresponding patent application(s), which are listed on the attached Submission Under MPEP 609 D.
- ☐ Attached are the following non-published pending patent applications which may be deemed relevant, which are listed on the attached Submission Under MPEP 609 D.
- ☒ *Fee Authorization.* The Commissioner is hereby authorized to charge the above-referenced fees of \$0.00 and charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. 23-2415 (Docket No. 12636.330.201).

Respectfully submitted,

WILSON SONSINI GOODRICH & ROSATI

Dated: 06/11/04

By: Maya Skubatch
Maya Skubatch, Reg. No. 52,505

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Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Complete if Known

Application No.	10/613,222
Filing Date	07/03/2003
First Named Inventor	Rubinfeld
Art Unit	1642
Examiner Name	Nickol
Attorney Docket No.	12636.330.201

Sheet 1 Of 2

U.S. PATENT DOCUMENTS

Examiner's Initials	Cite No. 1	Document No.	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
		US-			
		US-			
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FOREIGN PATENT DOCUMENTS

Examiner's Initials	Cite No. 1	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³ - Number ⁴ - Kind Code ⁵ (if known)				
		WO 02/069903	09/12/2002	Biocryst Pharmaceuticals, Inc.		
EXAMINER SIGNATURE				DATE CONSIDERED		

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional) 2 See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST. 3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached.

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Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Complete if Known		
				Application No.	10/613,222	
				Filing Date	07/03/2003	
				First Named Inventor	Rubinfeld	
				Art Unit	1642	
				Examiner Name	Nickol	
Sheet	2	Of	2	Attorney Docket No.		12636.330.201

OTHER PRIOR ART – NON PATENT RELATED DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of author (in CAPITAL LETTERS), title of the article (when appropriate), title of the Item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s) publisher city and/or country where published	T ²
		GOFFIN, J. et al., "DNA methyltransferase inhibitors—state of the art", <i>Annals of Oncology</i> , 2002, pages 1699-1716, Vol. 13.	
		SHEIKHNEJAD, G. et al., "Mechanism of inhibition of DNA (cytosine C5)-methyltransferases by oligodeoxyribonucleotides containing 5,6-dihydro-5-azacytosine", <i>J. Mol. Biol.</i> , 1999, pages 2021-2034, Vol. 285.	
		WIJERMANS, P. et al., "Low-dose 5-aza-2'-deoxycytidine, a DNA hypomethylating agent, for the treatment of high-risk myelodysplastic syndrome: a multicenter phase II study in elderly patients", <i>Journal of Clinical Oncology</i> , March 2000, pages 956-962, Vol. 18, No. 5	
EXAMINER SIGNATURE		DATE CONSIDERED	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.